PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ULB-018-PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/07453	International filing date *(day/month/year)* 10.07.2003	Priority date *(day/month/year)* 10.07.2003
International Patent Classification (IPC) or both national classification and IPC B01L3/00		
Applicant UNIVERSITE LIBRE DE BRUXELLES et al.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04.02.2005	15.11.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Tiede, R Telephone No. +31 70 340-1090

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/07453

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-56 as originally filed

Claims, Numbers

1-61 as originally filed

Drawings, Sheets

1/30-30/30 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1,4,18-61
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-61
Industrial applicability (IA)	Yes:	Claims	1-61
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: STORDEUR P ET AL: "Immune monitoring in whole blood using real-time PCR" JOURNAL OF IMMUNOLOGICAL METHODS, ELSEVIER SCIENCE PUBLISHERS B.V.,AMSTERDAM, NL, vol. 276, no. 1-2, 1 May 2003 (2003-05-01), pages 69-77, XP004422642 ISSN: 0022-1759

D2: US-A-5 362 654 (POULETTY PHILIPPE) 8 November 1994 (1994-11-08)

1 The wording of claim 1 is vague and unclear (Article 6 PCT). The relation between the container and vessel in claim 1 is unclear, from the wording of the claim and the description a vessel and a container next to each other (on a table) would comprise a physical barrier at the same time. According to the description in reference to figure 11 (page 33 and page 15 line 27ff, where an embodiment of the claimed invention is disclosed), the connection between the container and the vessel is established during use by a coupling for example of a Luer-type. Thus, it remains unclear by which technical features a connection shall be restricted. It remains open wether the connection is actually engaged and leads to a fixed relationship between vessel and container or not, and furthermore by which technical features a connection is actually restricted. Is a connection established by pouring a reagent from a container into the vessel or by pipetting a reagent from a pipette tip (a container) to the vessel? Consequently, the intended scope of claim 1 remains unclear.

2 As far as claim 1 can be understood, it does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. The document D1 discloses (the references in parentheses applying to this document):

2.1 A vessel with a first substance (eg. heparinized blood or LPS and heparinized blood) and a container with a second substance (PAXgene reagent), a temporal physical barrier and some sort of connection between vessel and container is implicitly disclosed as otherwise the reagent cannot be added in a later stage of the

experiment as disclosed in D1 in the description of fig. 1 (see also point 1).

3 Similar arguments as outlined under point 1 and 2 can be levelled against claims 24, 25, 31, 32 and 33. Thus these claims also lack novelty in view of D1 respectively (Article 33(2) and (3) PCT).

4 Dependent claims 2-23, 26-30, 34-61 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1 and the corresponding passages cited in the search report.

5 Note that additional features of claims 6-13, and 17 relate to features commonly known for sample test tubes. The skilled person would therefore regard it as a normal design option to include these features in the vessel described in document D1 in order to solve the problem posed and the subject-matter is therefore not inventive (Article 33(3) PCT).

6 Although claims 1 and 33 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.